

## **REMARKS**

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 42-48, 51-64 and 70-76 are pending in this application. Claims 42, 54-56, 58, 60, 63, 64, 70 and 74 are amended. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claim are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

#### **Specification**

The specification was objected to because that status of the related applications had not been updated. The specification is amended to add the patent number of U.S.S.N. 09/884,514.

No correction of sequence identifiers is required. All of the sequences shown in the figures and the sequence listing are provided with sequence identifiers on page 13 of the specification.

Reconsideration and withdrawal of the objections to the specification are requested.

#### **Claim Objections**

Claims 42-48, 51-62 and 74-76 were objected to because the claims do not require inactivation or attenuation of the isolated PCV2. Claim 42 has been amended to recite that the PCV2 is inactivated or attenuated.

Claim 59 was objected to because the word spacing in line 3 is allegedly improper. The word spacing is not improper. The chemical name for avridine is N,N-dioctadecyl-N',N'-bis(2-hydroxyethyl)propanediamine, with no spaces. (See attached Chemindustry listing for avridine.)

Claim 74 was objected to because the remarks cited in parentheses are allegedly unnecessary. Claim 74 has been amended to remove the recitations of the illnesses associated with the viruses.

Reconsideration and withdrawal of the claim objections are requested.

**Petition to Correct Inventorship under 37 CFR 1.48(a)**

A Petition to Correct Inventorship is not required for this application. A Petition to Correct Inventorship was filed and granted in the grandparent application (U.S.S.N. 09/161,092, now U.S. Patent No. 6,391,314) prior to the filing of this application. A copy of the corrected, executed Declaration, naming all ten inventors, was filed with this application. An additional copy is attached for the Examiner's ease of reference.

The Examiner's attention is directed to MPEP § 602.05(a), the last paragraph of which states:

A continuation or divisional application filed under 37 CFR 1.53(b) of a prior application in which a petition (or request) under 37 CFR 1.48 to add an inventor was filed should be filed with a copy of the executed declaration naming the correct inventive entity from the prior application or a newly executed declaration naming the correct inventive entity. A copy of any decision under 37 CFR 1.48 from the prior application is not required to be filed in the continuation or divisional application. (Emphasis added.)

A "copy of the executed declaration naming the correct inventive entity from the prior application" is exactly what was filed in this application. As such, nothing further is required.

**II. THE REJECTION UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, IS OVERCOME**

Claims 43-48, 53 and 74-76 were rejected under Section 112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The Examiner's attention is drawn to the record of parent application U.S.S.N. 09/884,514, in particular to the Amendment filed on March 7, 2003, which stated that the PCV2 strains of the invention have been deposited under the terms of the Budapest Treaty. That statement is repeated here verbatim.

The undersigned states that he is a registered patent attorney representing the Applicants, that the biological materials, accession nos. V97100219, V97100218, V97100217, V98011608 and V98011609, identified in the application as deposited, were deposited under the terms of the Budapest Treaty with the European Collection of Cell Cultures (ECACC), Centre for Applied Microbiology & Research, Porton Down, Salisbury, Wiltshire SP4 0JG, UK, and that:

- (a) during the pendency of this application, access to each of the Deposits will be afforded to the Commissioner upon request;

- (b) all restrictions upon availability of the each of the Deposits to the public will be irrevocably removed upon granting of the patent;
- (c) each of the Deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of each of the Deposits was made; and
- (e) each of the Deposits will be replaced if it should ever become inviable.

Section 2404.01 of the MPEP states that a biological deposit is not necessary if the material is “known and readily available.” Indicia include “commercial availability, references to the biological material in printed publications, declaration of accessibility by those working in the field, evidence of predictable isolation techniques, or an existing deposit.” (Emphasis added.) PK/15 cells are commercially available, and can be ordered, for example, from the American Type Culture Collection. (See attached order form.) In addition, there are numerous references to PK/15 cells in printed publications. For example, a search of the USPTO database for issued patents containing “PK 15 cells” returned 59 hits. The same search in PubMed returned 94 hits. PK/15 cells are “known and readily available,” as required by MPEP 2404.01.

Based on these statements and arguments, reconsideration and withdrawal of the enablement rejection are requested.

### **III. THE DOUBLE-PATENTING REJECTIONS ARE OVERCOME**

Claims 42 and 49-76 were rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27, 29 and 30 of U.S. Patent No. 6,217,883. Claims 42-76 were rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-12 and 14-25 of U.S. Patent No. 6,953,581. Solely to expedite prosecution and without agreeing with the substance of the rejection, a Terminal Disclaimer to the cited patents is enclosed. Reconsideration and withdrawal of the double-patenting rejections are requested.

**CONCLUSION**

The application is believed to be in condition for allowance. Favorable reconsideration of the rejections and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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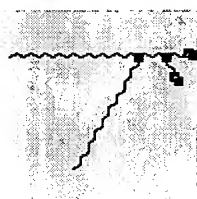
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a chemical name, CAS Number, or molecular formula. Use \* for partial names (i.e. chloro\*)

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**Synonyms:** 2,2'-((3-(Diocetadecylamino)propyl)imino)bisethanol, 2,2'-((3-(Diocetadecylamino)propyl)imino)diethanol, 35607-20-6, AVRIDINE, Avridina [Spanish], Avridine [USAN:INN], Avridinum [Latin], BRN 2227682, CP 20961, Ethanol, 2,2'-((3-(diocetadecylamino)propyl)imino)bis-, N,N-Diocetadecyl-N',N'-bis(2-hydroxyethyl)propanediamine, AIDS-212544, AIDS212544, CP-20,961, N,N-Diocetadecyl-N',N'-bis(2-hydroxy-ethyl)propanediamine

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Search for: AVRIDINE

IUPAC  
Name 2-(3-  
dioctadecylaminopropyl-  
(2-hydroxyethyl)amino)  
ethanol

CAS  
Number 35607-20-6

Chemical  
Formula  $C_{43}H_{90}N_2O_2$

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| Organism:                                   | <i>Sus scrofa</i> (pig)  | Morphology:                     | epithelial                |
| Source:                                     | Organ: kidney<br>Disease: normal   |                                 |                           |
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| <b><i>Related Cell Culture Products</i></b> |  |                                 |                           |
| Virus Susceptibility:                       | hog cholera; African swine fever; vesicular exanthema of swine; foot and mouth disease (FMDV); vesicular stomatitis (Indiana); vaccinia; reovirus 2, 3; adenovirus 4, 5; coxsackievirus B2, B3, B4, B5, B6   |                                 |                           |
| Virus Resistance:                           | poliovirus 2   |                                 |                           |
| Reverse Transcript:                         | positive   |                                 |                           |

|                          |  |
|--------------------------|--|
| <b>Age:</b>              | adult  |
| <b>Comments:</b>         | <p>The presence of a porcine papovavirus in PK(15) cells has been reported in cells obtained from multiple sources including the ATCC. [53398] [53399]</p> <p>The Foreign Animal Disease Diagnostic Laboratory of the US Department of Agriculture has determined that ATCC CCL-33 is not infected with Hog cholera virus or African swine fever virus, and uses this line to screen for those viruses. [5588]</p> <p>The cell line harbors an endogenous C-type retrovirus. [26185] [53399] [56104]</p> <p>The cells are positive for porcine circovirus (PCV) antigens.</p> <p>The cells are positive for keratin by immunoperoxidase staining.</p>  |
| <b>Propagation:</b>      | <p><b>ATCC complete growth medium:</b> Minimum essential medium (Eagle) with 2 mM L-glutamine and Earle's BSS adjusted to contain 1.5 g/L sodium bicarbonate, 0.1 mM non-essential amino acids, and 1.0 mM sodium pyruvate, 90%; fetal bovine serum, 10%</p> <p><b>Temperature:</b> 37.0C</p>  |
| <b>Subculturing:</b>     | <p>Rinse the cell sheet 2 times with fresh 0.25% trypsin, 0.03% EDTA solution, remove trypsin and allow the culture to stand at room temperature for 5 to 10 minutes. Add fresh medium, aspirate and dispense into new flasks.</p> <p><b>Subcultivation ratio:</b> A subcultivation ratio of 1:2 to 1:4 is recommended</p> <p><b>Medium renewal:</b> 2 to 3 times per week</p>   |
| <b>Preservation:</b>     | culture medium 95%; DMSO, 5%   |
| <b>Related Products:</b> | Recommended medium (without the additional supplements or serum described under ATCC Medium): ATCC 30-2003<br>recommended serum: ATCC 30-2020  |
| <b>References:</b>       | <p>22988: Dulac GC , Afshar A . Porcine circovirus antigens in PK-15 cell line (ATCC CCL-33) and evidence of antibodies to circovirus in Canadian pigs. Can. J. Vet. Res. 53: 431-433, 1989. PubMed: 2686830</p> <p>26184: Pirtle EC , Woods LK . Cytogenetic alterations in swine kidney cells persistently infected with hog cholera virus and propagated with and without antiserum in the medium. Am. J. Vet. Res. 29: 153-164, 1968. PubMed: 4965860</p> <p>26185: Armstrong JA , et al. C-type virus particles in pig kidney cell lines. J. Gen. Virol. 10: 195-198, 1971. PubMed: 4324256</p> <p>53398: Newman JT , Smith KO . Characteristics of a swine papovavirus. Infect. Immun. 5: 961-967, 1972. PubMed: 4344097</p> <p>53399: Tumilowicz JJ , et al. Concurrent replication of a papovavirus and a C-type virus in the CCL 33 porcine cell line. In Vitro 15: 922-928, 1979. PubMed: 232060</p> <p>56104: Todaro GJ , et al. Characterization of a type C virus released from the porcine cell line PK(15). Virology 58: 65-74, 1974. PubMed: 4132403</p> <p>5588: James A House , personal communication</p> |

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